IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GREGORY W. BARAN , M.D. Plaintiff, v. MEDICAL DEVICE TECHNOLOGIES, INC., et al., Defendant.	)	CASE NO. 1:04cv1251 JUDGE KATHLEEN O'MALLEY

EXPERT REPORT OF MAJID RASHIDI, Ph.D., P.E.

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EXPERT REPORT OF MAJID RASHIDI, PH.D, P.E.

I, Majid Rashidi, Ph.D., P.E., am a United States citizen residing in Pepper Pike, Ohio. I have been retained by Defendant, Medical Device Technologies, Inc. ("MDTech") as an expert in the above referenced matter to provide study, consultation, opinions, conclusions, evidence and testimony pertaining to issues related to this matter.

I. TERMS OF THE ENGAGEMENT

According to the terms of my engagement by Defendant, MDTech, I am being paid $200 per hour, plus expenses.

II. EDUCATION AND TECHNICAL/PROFESSIONAL EXPERIENCE

A copy of my *curriculum vitae* is attached as Exhibit 1.

III. EXPERIENCE AS A TESTIFYING EXPERT

In the past several years, I have given evidence through expert statements, by deposition or in court, as shown in the list accompanying my curriculum vitae, attached as Exhibit 1.

IV. INFORMATION AND DOCUMENTS REVIEWED

The data, documents and other information I have reviewed and considered in connection with this opinion include the following:

I have examined two samples of the MDTech products (the "accused product"). One of the samples was in a disassembled condition for observing and examining the internal parts that are housed within its handle. The second product was intact, in a condition for its intended use.

I have read and studied U.S. Patent No. 5,025,797 (the "'797 patent"), a copy of which is attached as Exhibit 2.

In connection with this report, I have also reviewed the Court's Memorandum of Opinion & Order dated September 25, 2007, (the "Order") and the patents identified below.

U.S. Patents

U.S. Patent No. 3,394,699 to Koett;
U.S. Patent No. 3,561,429 to Jewett;
U.S. Patent No. 4,600,014 to Beraha;
U.S. Patent No. 4,699,154 to Lindgren;
U.S. Patent No. 4,735,215 to Goto;
U.S. Patent No. 4,776,346 to Beraha;
U.S. Patent No. 4,817,631 to Schnepp-Pesch;
U.S. Patent No. 4,881,551 to Taylor;
U.S. Patent No. 4,893,635 to de Groot;
U.S. Patent No. 4,907,599 to Akerfeldt;
U.S. Patent No. 4,924,878 to Nottke;
U.S. Patent No. 4,944,308 to Akerfeldt;

I have also reviewed:

1. Dr. Baran's Claim Construction Briefs;
2. Defendants' Claim Construction Briefs.
3. Expert Report of John R. Haaga, M.D.
4. Deposition of Christopher J. Blake, June 30, 2005, Pages 133-136

V. SUMMARY OF OPINIONS

I have been told that Dr. Gregory W. Baran, ("Dr. Baran" or "Plaintiff") has asserted that MDTech infringes Claim 7 of the '797 patent. I will address whether the products[1] marketed by Defendant are read on by Claim 7 of the '797 patent in this report. **It is my opinion that the accused product of the Defendant does not infringe on Claim 7 of the '797 patent, as asserted by the Plaintiff.**

[1] Here "accused product" refers to the Full Core Biopsy Instruments marketed by MDTech under the brand name BioPince. While there are several sizes of the BioPince, they show a basic design such that this analysis covers all model numbers.

VI. TECHNOLOGY OF THE PATENT IN SUIT

The '797 patent teaches an automated biopsy instrument having (with reference to Fig. 1 of the patent) a support rod **42** with a stylet **60** secured thereto. The support rod is positioned within a casing **12** having the form of a elongated hollow cylindrical tube. The instrument further includes a cannula **66** that is telescopically sleeved over the stylet and secured to a guide **18** by a cannula mount **58**. The guide is also positioned within the casing. A compression coil spring **16** is positioned coaxially over the support rod **42** and is positioned between a disc-shaped base **44** from which the support rod extends. As will be explained below, the spring stores elastic potential energy which, upon release, drives the cannula into human tissue for collecting a tissue sample.

A single component charging member **20** sleeves over the casing and is capable of longitudinally reciprocating thereon. Upon sliding this single component charging member in a rearward direction, two fingers **94** that are rigidly attached to the member engage the guide through elongated slots **40** formed in the casing to compress the spring. The spring is held in a compressed position via a single latching projection **102** of a lever **22**, thereby providing a "charged" condition for the biopsy instrument.

The lever **22** is rigidly extended along the longitudinal axis of the casing to provide a trigger arm to be activated by the thumb or other fingers of the physician to "discharge" the instrument and cause the cannula to pierce into the targeted tissue. At the end of the charging phase, the single component charging member remains stationary and covers the trigger arm of the latch, acting as a "trigger-safety" component. To make the instrument ready for "discharge"

or firing, the physician must slide the single component charging member forward toward the distal end of the instrument in order to expose the trigger arm.

VII. TECHNOLOGY OF THE ACCUSED PRODUCT

Figures 1-A through 1-G of this report depict pictures of an accused product in different configurations along with its exposed internal components. The accused product provides an automated instrument for obtaining core biopsy samples from tissue. With reference to Figures 1-A, 1-B and 1-D, the sampling portion of the instrument includes an inner cannula **10** inside an outer tube **12**. The outer tube has a pincer portion for assisting in collection and retention of the biopsy sample. The cannula includes a slot for receiving the pincer of the outer tube. The cannula and outer tube are attached to interlocking guides, indicated in general at **14** in Figure 1-D (and at **14** in Figure 1-C). As illustrated in Figures 1-D and 1-F, the back guide **16** is the cannula guide and the front guide **18** is the outer tube's guide. The cannula is positioned in a V-shaped trough on the back guide and is permanently held in place by adhesive. The outer tube is positioned in a V-shaped trough on the front guide and is permanently held in place by adhesive. The front and back guides are connected in such a way that they can move together when being placed into a charged position, as well as during the first part of the spring-propelled discharge, but can also move separately during the final stage of the discharge stroke. As illustrated in Figure 1-E, a stylet **20** is disposed within the cannula. The stylet is a solid needle and does not have a notch in the distal end. A region near the proximal end of the stylet is permanently and directly attached by adhesive to a plastic stylet retaining block **22** (Figure 1-E).

The cannula and stylet are enclosed in a generally hollow rectangular housing, indicated at **24** in Figures 1-A through 1-C. The stylet retaining block is held in a fixed position within the housing. Both guides **14** can slide within the housing, subject to the resistance of a spring, **26** in

Figure 1-C. As illustrated in Figure 1-C, the spring **26** is disposed between the back guide (to which the cannula is attached) and the housing in the region in which the stylet retaining block is positioned. The instrument is a single procedure disposable instrument and is not designed to allow exchange or replacement of the stylet or cannula. Neither the cannula, outer tube nor the stylet can be removed from the housing without destroying the instrument.

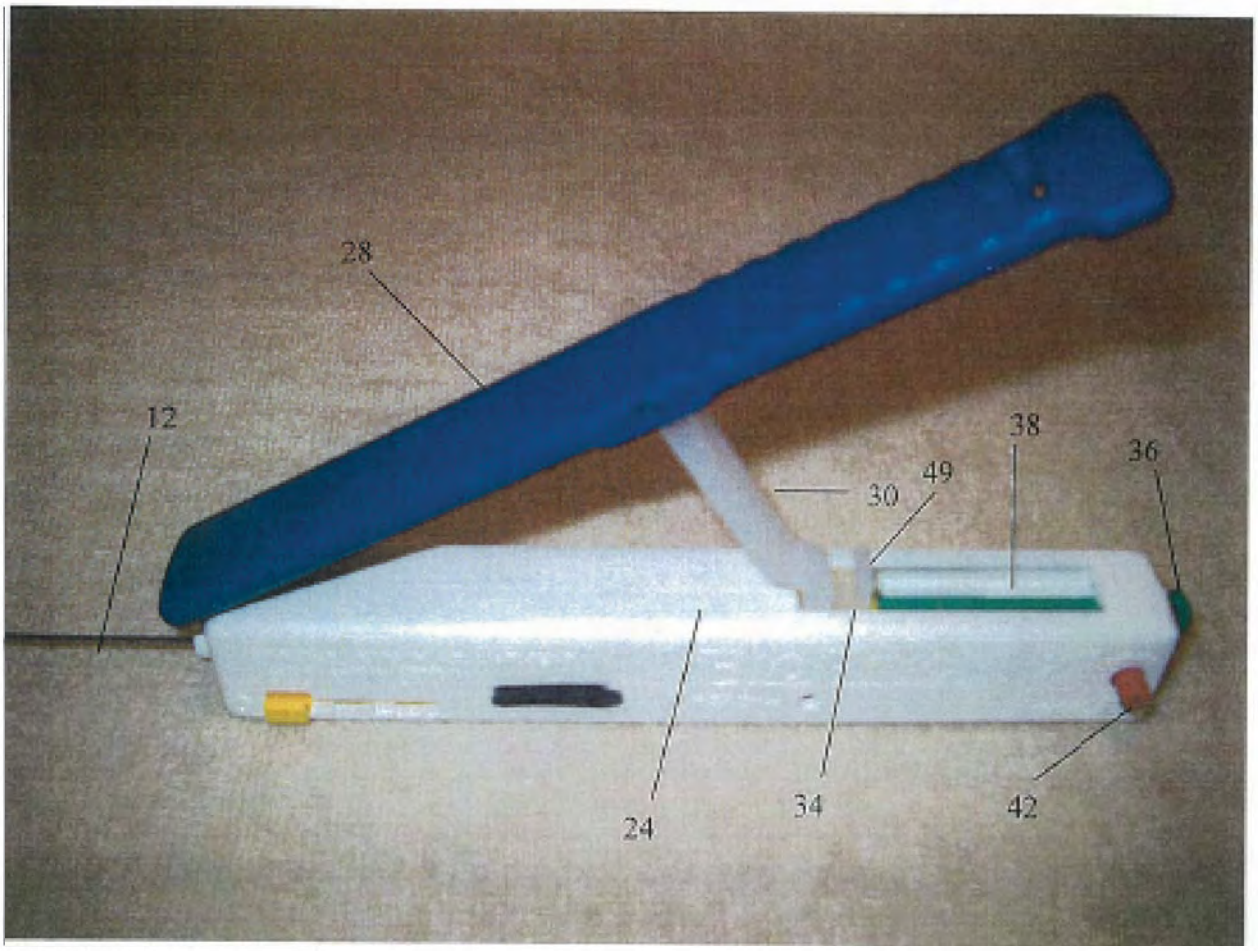

Figure 1-A - The accused product sample in its startup position for charging

12 – Outer Tube

24 – Housing

28 – Crank Arm

30 – Connecting Rod

34 – Crank Arm Fixer

36 – Trigger Button

38 – Elongated Release Bar

42 – Safety Button

49 – Crank Arm Locking Tab

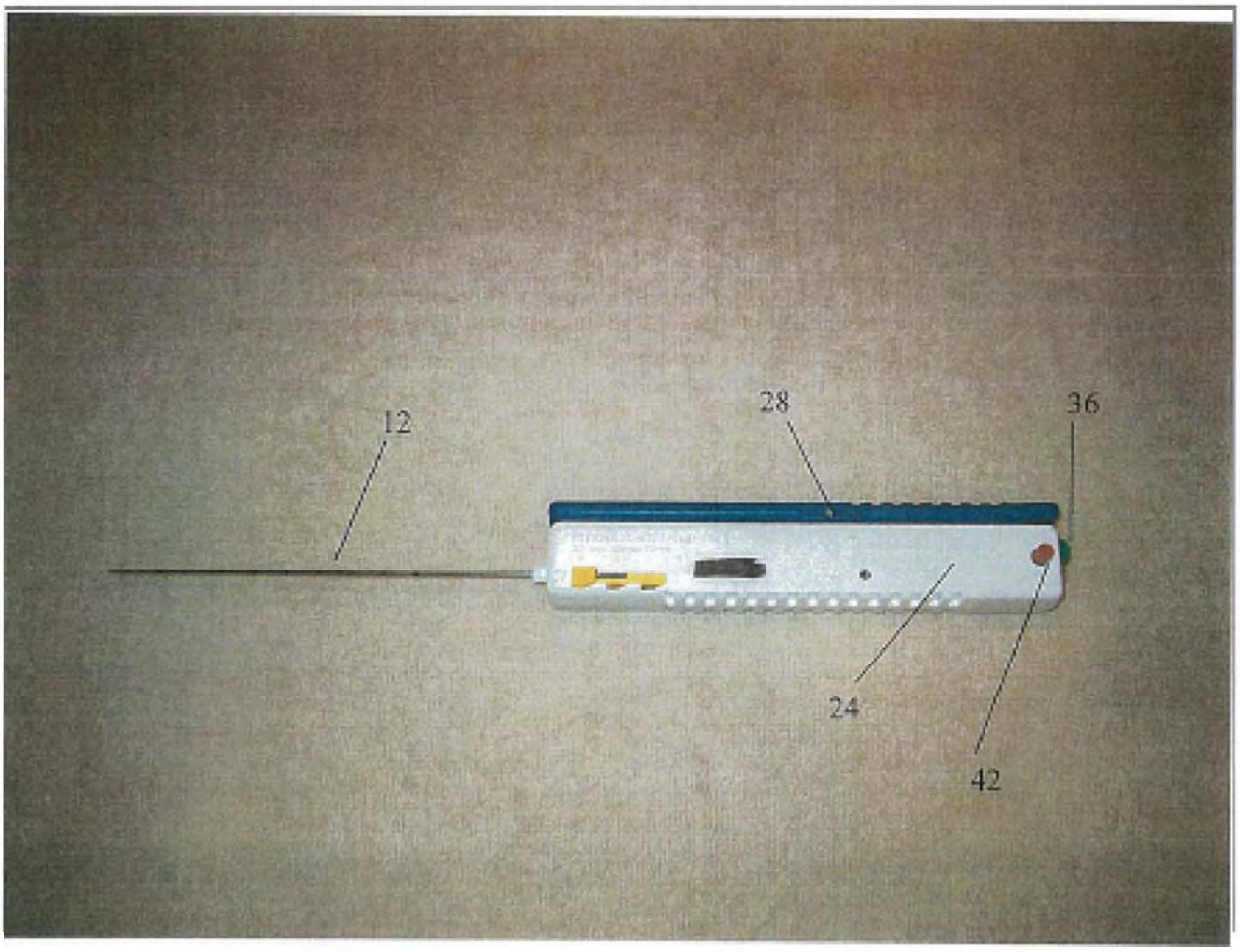

Figure 1-B - The accused product sample in its charged and ready-to-use configuration.

12 – Outer Tube

24 – Housing

28 – Crank Arm

36 – Trigger Button

42 – Safety Button

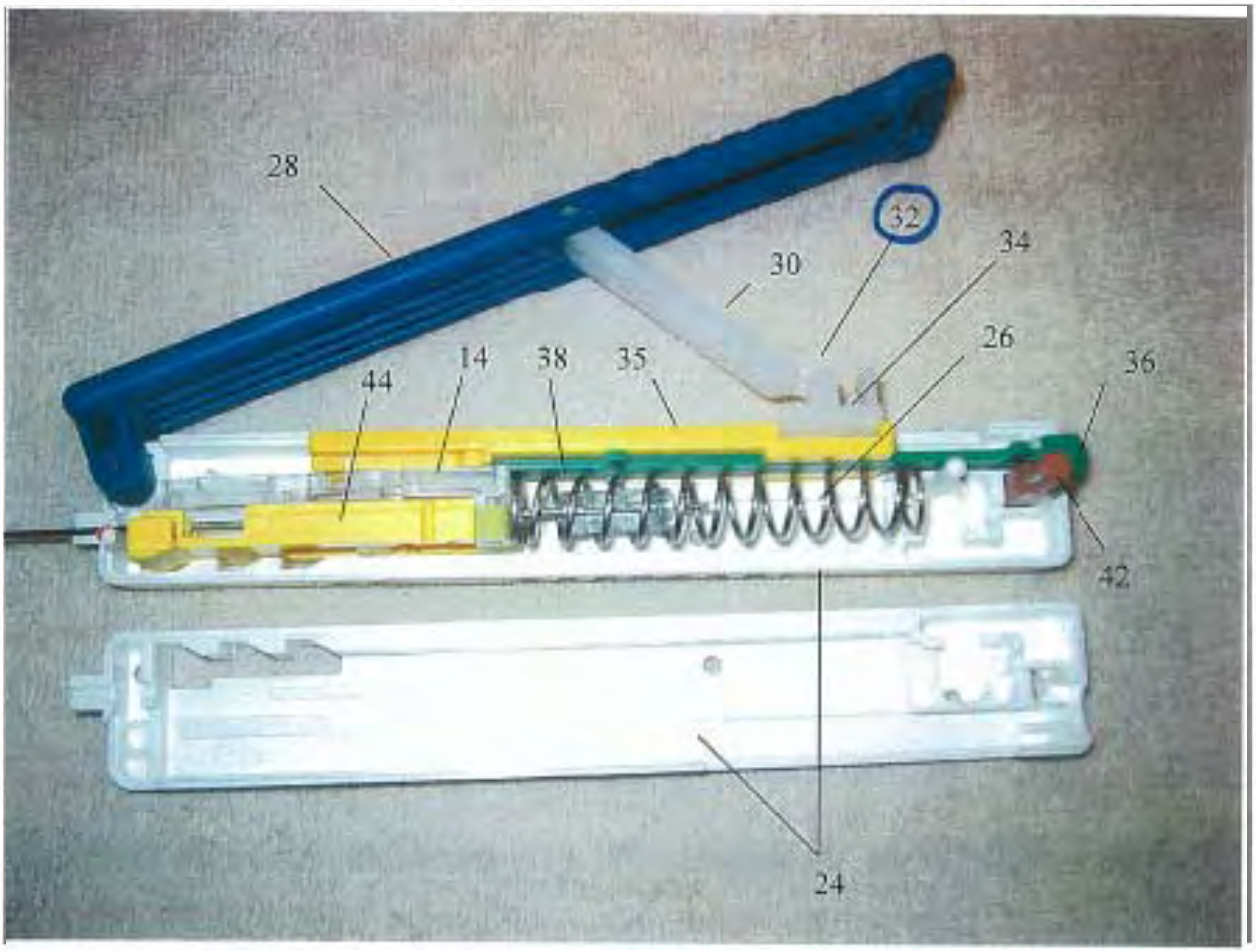

Figure 1-C - The accused product with its housing opened to show the internal parts.

14 – Interlocking Front and Back Guides

24 – Housing

26 - Spring

28 – Crank Arm

30 – Connecting Rod

34 – Crank Arm Fixer

38 – Elongated Release Bar

35 – Slider Link

42 – Safety Button

36 – Trigger Button

44 – Guide Stop

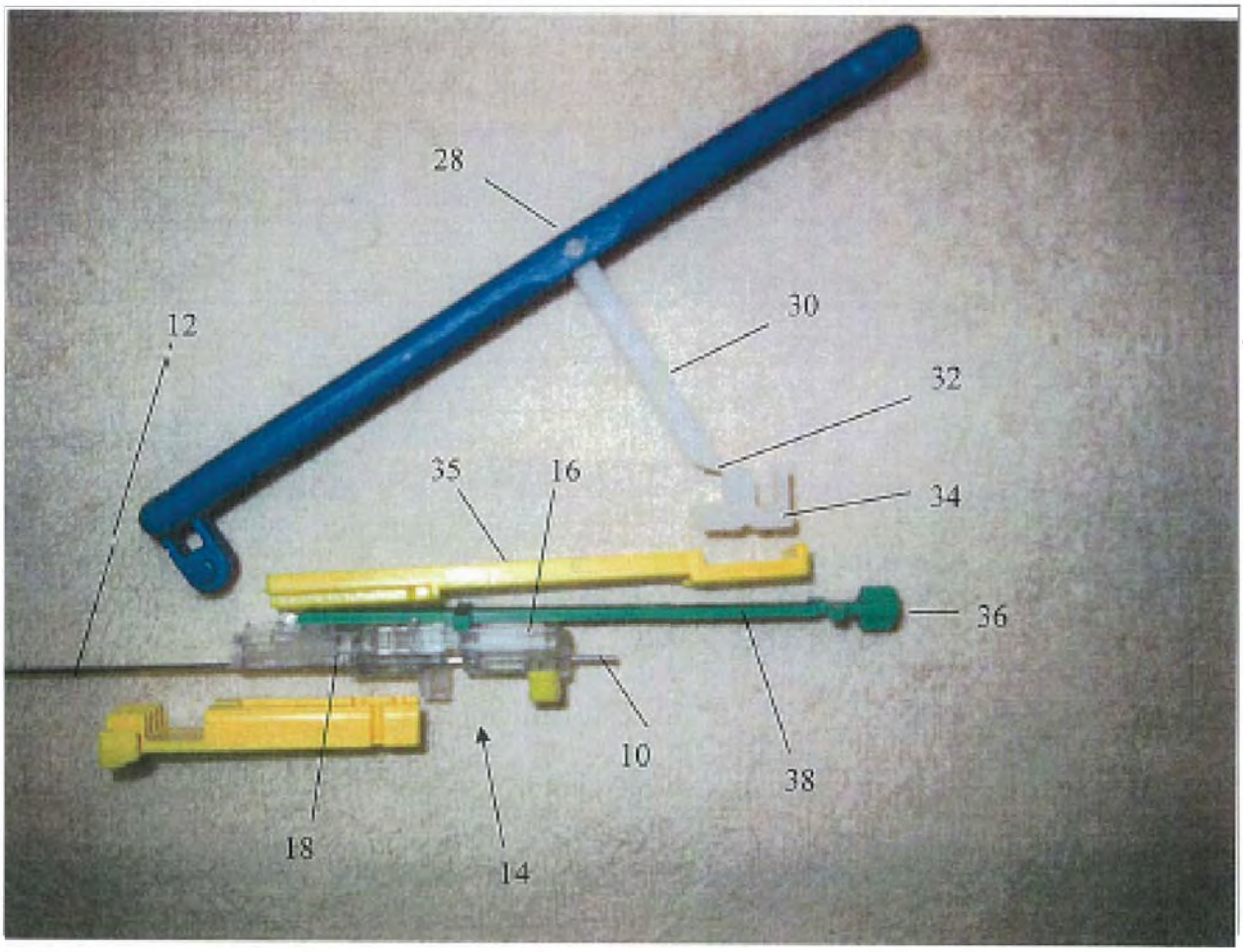

Figure 1-D - The components of the slider crank mechanism of the accused product in a disassembled condition.

10 - Cannula

12 – Outer Tube

14 – Interlocking Front and Back Guides

16 – Back Guide

18- Front Guide

28 – Crank Arm

30 – Connecting Rod

32 – Living Hinge

34 – Crank Arm Fixer

35 – Slider Link

36 – Trigger Button

38 – Elongated Release Bar

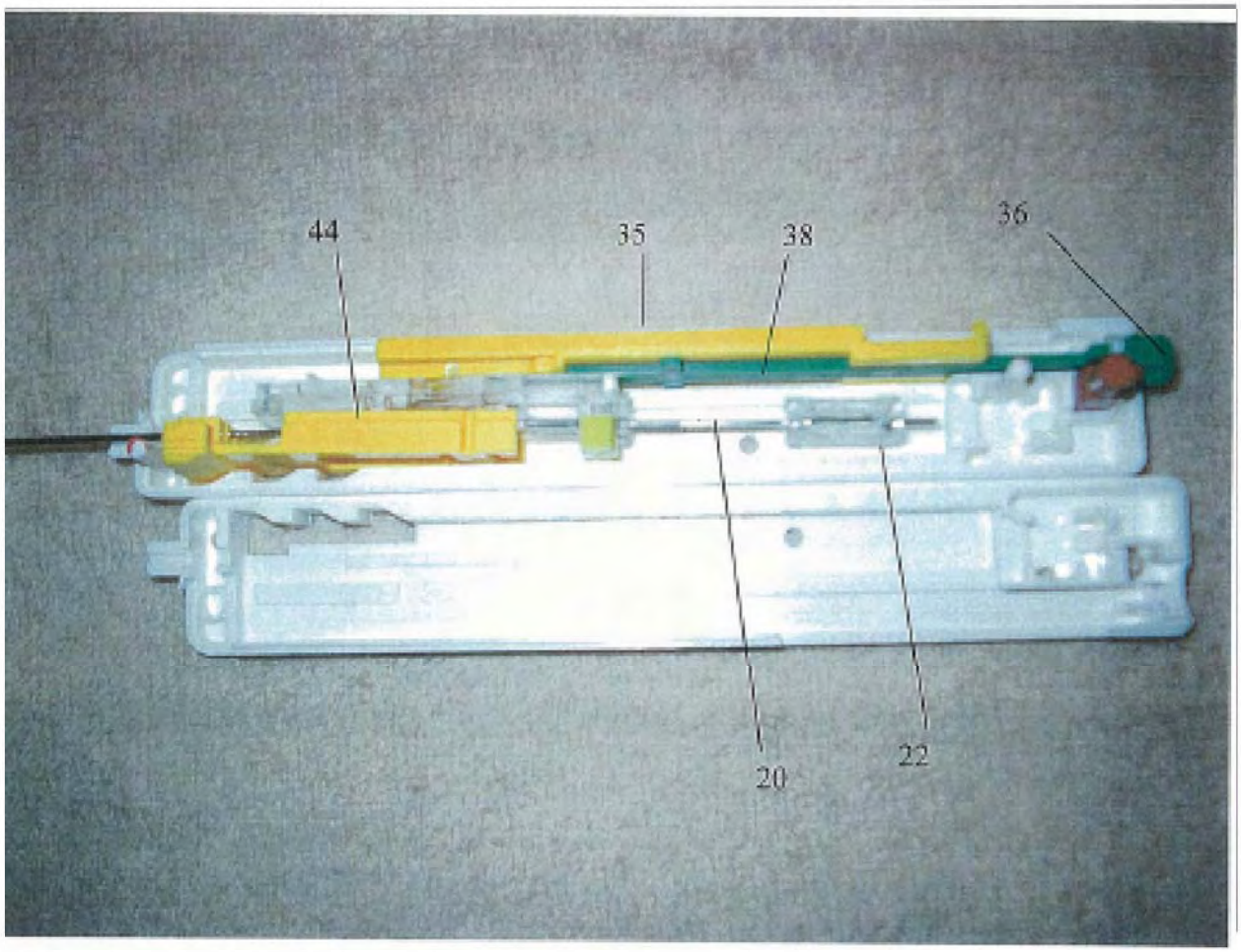

Figure 1-E – Arrangement of the retain and release components of the accused product sample.

20 – Stylet

22 – Stylet Retaining Block

35 – Slider Link

36 – Trigger Button

38 – Elongated Release Bar

44 – Guide Stop

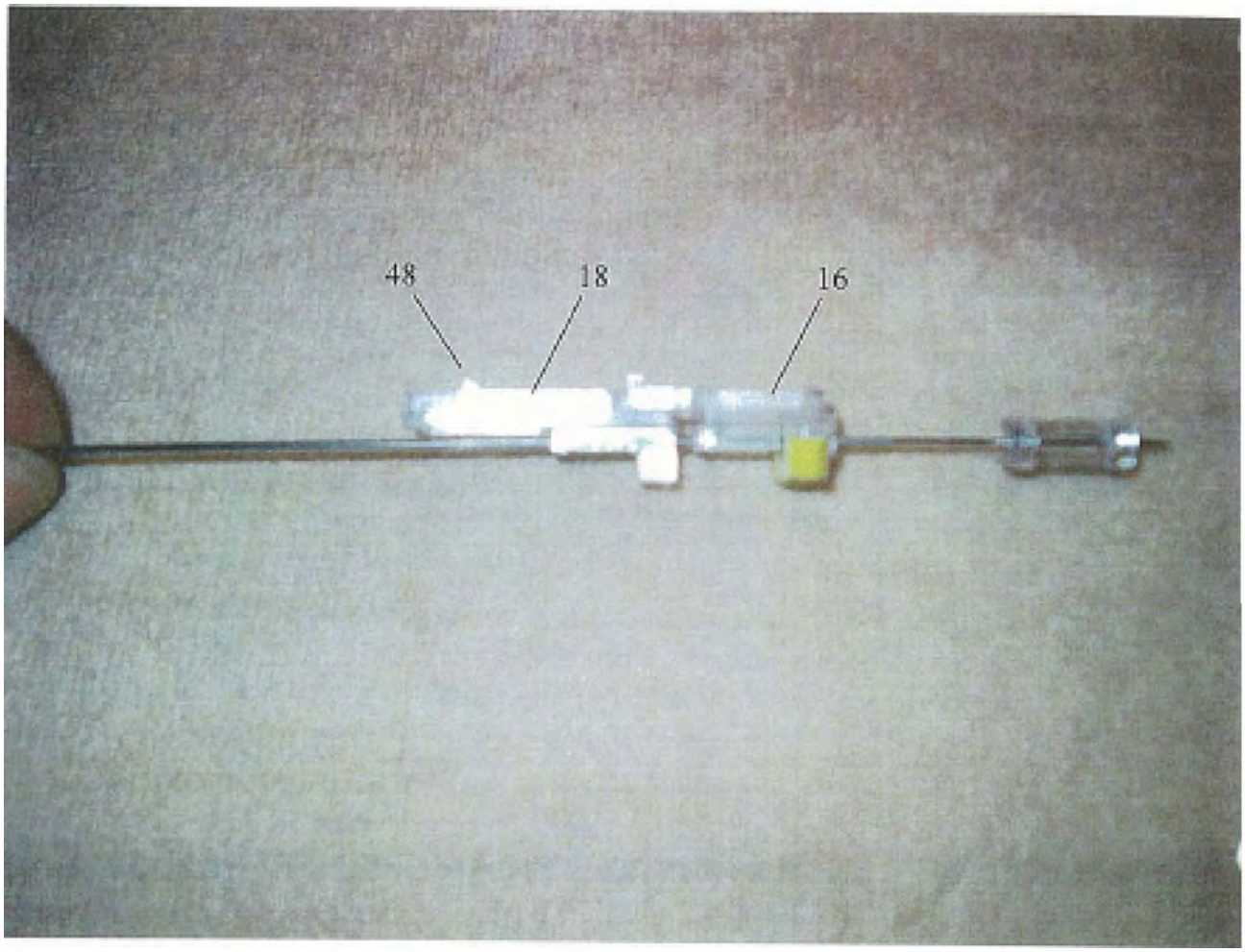

Figure 1-F – The latching protrusion provided on the front guide.

16 – Back Guide

18 – Front Guide

48 – Latching Protrusion

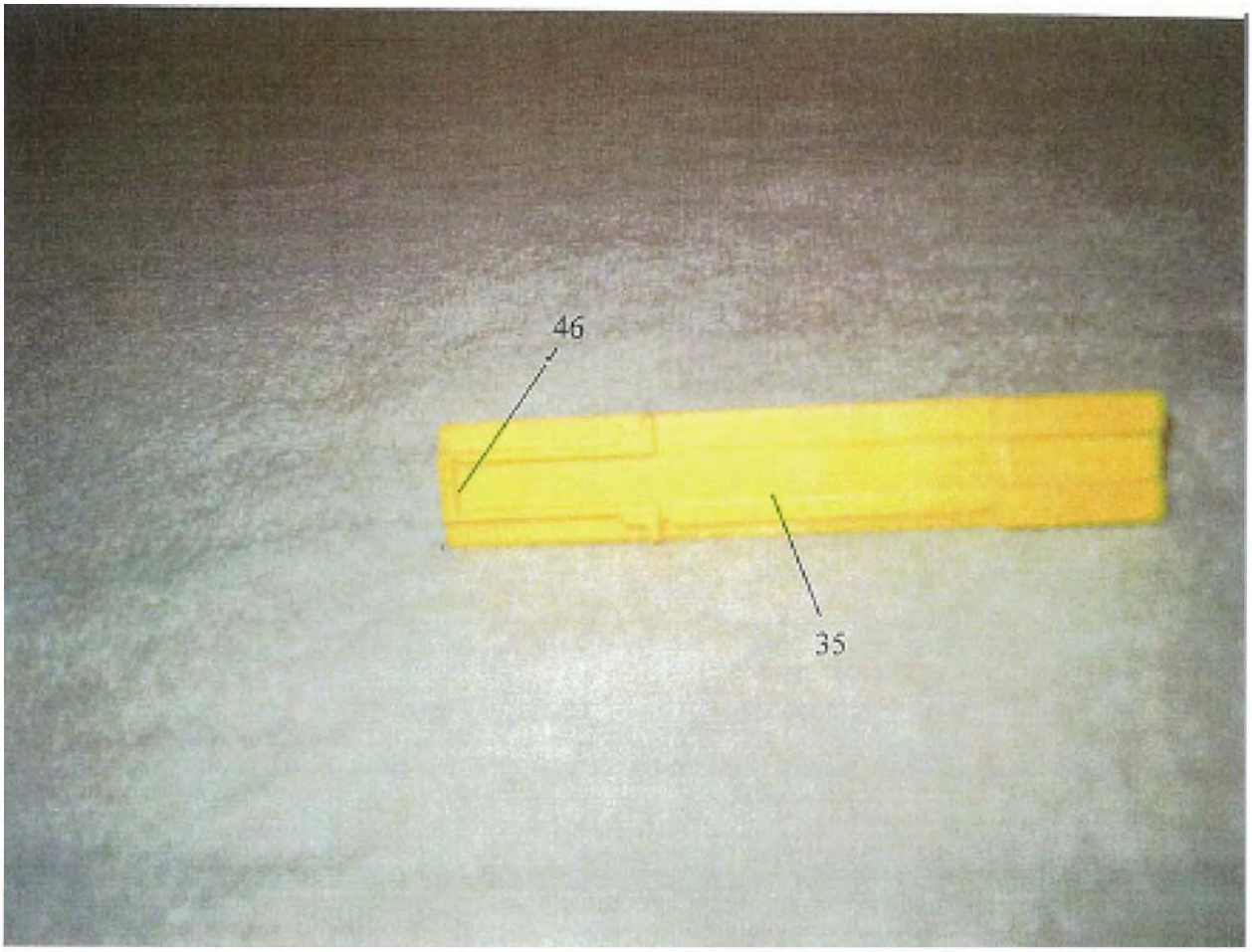

Figure 1-G - The step for receiving of the latching protrusion of Figure 1-F.

35 – Slider Link

46 - Locking Groove

The housing contains a slider-crank mechanism, illustrated in Figure 1-D. As illustrated in Figures 1-A through 1-D, on one side of the housing, there is a crank arm **28**. The crank arm is pivotally mounted to the distal end of the housing (such that the proximal end of the lever moves distally and away from the proximal end of housing). As illustrated in Figures 1-A, 1-C and 1-D, the crank arm is pivotally connected to a connecting rod **30** which is connected by a living hinge **32** to a crank arm fixer **34**. The crank arm fixer is engaged with the slider link (**35** in Figures 1-C through 1-E and 1-G) inside the housing. The slider link has a locking groove, illustrated at **46** in Figure 1-G, which can be engaged by a latching protrusion, illustrated at **48** in Figure 1-F, extending from the front (outer tube) guide during charging of the instrument.

As illustrated in Figures 1-A through 1-E, a trigger button **36** extends through the proximal end of the housing. The trigger button is the proximal end of an elongated release bar, illustrated at **38** in Figures 1-A, 1-D and 1-E, which, as illustrated in Figures 1-C through 1-E, is disposed between the slider link and both guides. The elongated release bar is sized such that when the trigger button is depressed, the elongated release bar disengages the latching protrusion of the front guide from the cocking groove of the slider link by way of a wedging action. A safety button, illustrated at **42** in Figures 1-A and 1-C, is disposed through each side of the proximal end of the housing. The safety button is the end of a safety rod which engages the elongated release bar. In the "Safe" position of the safety button, the safety rod locks the elongated release bar in its most proximal position preventing the trigger from being depressed. In the "Fire" position of the safety button, the safety rod disengages the elongated release bar thus allowing the trigger to be depressed to fire the instrument.

In order to operate the instrument, the user holds the housing with one hand and operates the crank arm with the other hand. Both hands of the user are required to cock the instrument.

With reference to Figure 1-A, the crank arm is moved forward by the user away from the housing. As the crank arm moves forward and away from the housing, the connecting rod **30** causes the crank arm fixer **34** to move towards the distal end of the housing. With reference to Figure 1-C, the crank arm fixer causes the slider link **35** within the housing to slide distally relative to the housing. When the slider link reaches its most distal position, illustrated in Figure 1-C, the latching protrusion on the front (outer tube) guide engages the locking groove in the slider link. Engagement of the front guide by the slider link also causes the back (cannula) guide to be forced into its distal position relative to the front guide. This moves the cannula distally relative to the finger tube. In this position the pincer does not protrude into the bore of the cannula.

The user then moves the crank arm towards the housing. As the crank arm returns towards the housing, the crank arm fixer is pushed by the connecting rod towards the proximal end of the housing. Because the latching protrusion of the front (outer tube) guide is engaged with the locking groove of the slider link, the front and back guides (**18** and **16** in Figure 1-D) are also moved by the slider link towards the proximal end of the housing. The spring (**26** in Figure 1-C) is compressed between the back guide and the housing. When the crank arm is in the fully closed position, illustrated in Figure 1-B, the crank arm becomes locked to the crank arm locking tab **49** of the crank arm fixer **34**. The slider link and the guides are locked in the charged position. At this point the cannula is fully withdrawn and loaded and the stylet is protruding from the tip of the cannula.

The instrument may then be positioned with the tip of the stylet adjacent a tissue to be sampled. With the instrument in position, the user pushes the safety button (**42** in Figures 1-A and 1-C) from the "Safe" position to the "Fire" position. The user then pushes the trigger button

(**36** in Figures 1-A through 1-E) to fire the instrument. When the trigger button is depressed, the distal end of the elongated release bar (**38** in Figures 1-D and 1-E) slides distally relative to the slider link and guides. The distal end of the elongated release bar contacts the latching protrusion of the front guide causing it to disengage the cocking groove in the slider link due to a wedging action.

When the latching protrusion of the front guide disengages the locking groove of the slider link, the guides are no longer held in their location at the proximal end of the housing. The compression in the coil spring consequently propels the guides forward with the distal end of the cannula advancing into the tissue to be sampled. When the back (cannula) guide contacts a guide stop, illustrated at **44** in Figures 1-C and 1-E, the forward progress of the cannula is arrested. However, the momentum of the front (outer tube) guide causes it to advance an additional few millimeters. The slight forward movement of the outer tube relative to the cannula allows the pincer of the outer tube to enter the bore of the cannula slicing off the tissue sample and allowing a full core to be extracted when the cannula is withdrawn from the tissue.

The instrument may then be removed from the patient thereby extracting the biopsy core which is retained in the distal portion of the cannula. After the instrument is removed from the patient, the crank arm is opened and closed again. This removes the pincer of the outer tube from the bore of the cannula and then retracts the cannula proximally relative to the stylet. The biopsy sample is thus pushed out of the distal portion of the cannula. The instrument is now charged and ready for taking another sample on the same patient if so desired.

VIII. LEVEL OF ORDINARY SKILL IN THE ART AND FIELD OF THE INVENTION

I understand that claims are interpreted from the perspective of a person having ordinary skill in the art at the time of the invention. It is also my understanding that the priority filing date of the '797 patent is March 29, 1989. A person of ordinary skill in the art of the '797 patent in March of 1989 would have been someone with an undergraduate degree in mechanical engineering or several years of experience in designing of spring-loaded or spring-activated instruments. Additionally, a person of ordinary skill in the art of would have skills in the areas of kinematics, dynamics and statics of machinery and linkages.

IX. QUALIFICATIONS

I have education, training and expertise in mechanical engineering, machine design, machine component design, and product design.

I have experience in design, development, and testing of hand operated deflectable tip cardiac electrophysiology catheters currently marketed in the United States. Additionally, I have been one of the two collaborators who prepared the 510 K applications for these catheters that received clearance from the Food and Drug Administration for interstate marketing.

I have 20 years of experience in kinematics/dynamics of machinery and design/analysis of mechanisms. I recently designed a wear-test simulator machine for examining the wear characteristics of artificial disk prostheses. The primary motion generators of this simulator are a set of kinematic mechanisms optimally designed to mimic motions and loadings similar to those of a human spine.

I may use various demonstrative exhibits in support of my testimony. These may include, but are not limited to, animations, photographs, drawings and samples of the accused product.

X. INFRINGEMENT ANALYSIS

I understand that in order to infringe on a particular claim of a patent, the accused product must include every element of the claim either literally or under the doctrine of equivalents. I understand that a doctrine of equivalents analysis must be applied to individual elements of a claim, and not the invention as a whole. I also understand that a traditional test for the doctrine of equivalents is the "function-way-result" test, that is, an element of the accused product must perform substantially the same function, in substantially the same way to achieve substantially the same result as the claim limitation in order for the element in the accused product to be considered an equivalent under the doctrine of equivalents.

It is also my understanding that "means plus function" limitations in claims are limited to the corresponding structure described in the specification, and equivalents thereof, for performing the specified function.

For the reasons that follow, it is my opinion that the accused product does not infringe Claim 7 of the '797 patent, either literally or under the doctrine of equivalents.

XI. CLAIM 7 OF THE '797 PATENT

Claim 7 of the '797 includes the elements listed in the table below.

'797 Patent Claim 7 Elements
7. A biopsy instrument comprising
an elongate hollow casing

a needle extending outwardly from the casing and having a cannula and a stylet received within the cannula
a stationary support mounted within the casing in fixed relation thereto and having means affixing the stylet thereto,
a cannula guide
a cannula mount affixing the cannula to the guide
the guide being completely enclosed by the casing for reciprocating movement therewithin relative to the stationary support between a charged position, wherein the cannula is retracted in a direction away from the distal end of the stylet, and a discharged position, wherein the cannula is displaced from the charged position in the direction of the distal end of the stylet
a coil spring engaged between the stationary support and the guide for urging the guide toward the discharged position
a manually operable charging member for moving the guide to the charged position against the urging of the coil spring
a release means for retaining the guide in the charged position.

The Court's Order provided construction of three disputed terms of claim 7 of the '797 patent.

The first term construed by the Court is the following:

"a cannula mount affixing the cannula to the guide"

According to the Court construction, the above term of claim 7 of the '797 patent is interpreted as:

> "a piece or structure which is independent from the structures which are the guide and the cannula serves the function of connecting the two other structures…that is **a structure or support which attaches or connects the cannula to the guide".**

Order, pp. 19-20.

The second term construed by the Court is the following:

"a manually operable charging member for moving the guide to the charged position against the urging of the coil spring"

According to the Court construction, the above term of claim 7 of the '797 patent is interpreted as:

"a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring."

Order, p. 26.

The Court also found "that member does not encompass 'mechanism'." Order, p. 25.

The third term is the following:

"a release means for retaining the guide in the charged position"

According to the Court construction, the above term of claim 7 of the '797 patent is interpreted as a means plus function element in which the function is:

"retaining the guide in the charged position and releasing, or setting free, the guide from the charged position."

Order, pp. 30-31.

The Court found the corresponding structure to be the "release lever **22**" with "the finger rest **98**", the "mount section 98", with the latching projection **102** at one end of the release having "flexibly secured to the outer casting with a spot weld **104**." For the single use embodiment. Order, p. 33. With respect to the reusable embodiment, the structure is identified as the release sever **222**, including the latching projection **302** and mounting section **298**. Order p. 50.

XII. THERE IS NO CANNULA MOUNT

As noted above, Claim 7 of the '797 patent recites the following:

"a cannula mount affixing the cannula to the guide"

According to the Court construction, the above term of claim 7 of the '797 patent is interpreted as:

"a structure or support which attaches or connects the cannula to the guide"

The Court also noted that the cannula mount is "a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures." Accordingly; there must be a standalone entity that can be defined as the cannula mount, that is, the cannula and the guide cannot to be considered to be parts of the "**structure or support.**"

In the accused product, each of the guides is formed with a V-shaped trough on top. The proximal end of the cannula lays in the trough of the back guide. The proximal end of the outer tube lays in the front guide. Glue is used to bind the cannula and outer tube to their respective guides, as shown in Figure 2. For the following reasons, such an adhesively bounded connection cannot be considered to be **a structure or support** literally or under the doctrine of equivalents.

As a person having ordinary skill in the art, it is my understanding that the cannula mount of claim 7 of the '797 patent is a standalone component and therefore must be **fabricated** separately from the guide and cannula. This structure must then be attached to the cannula and then to the guide.

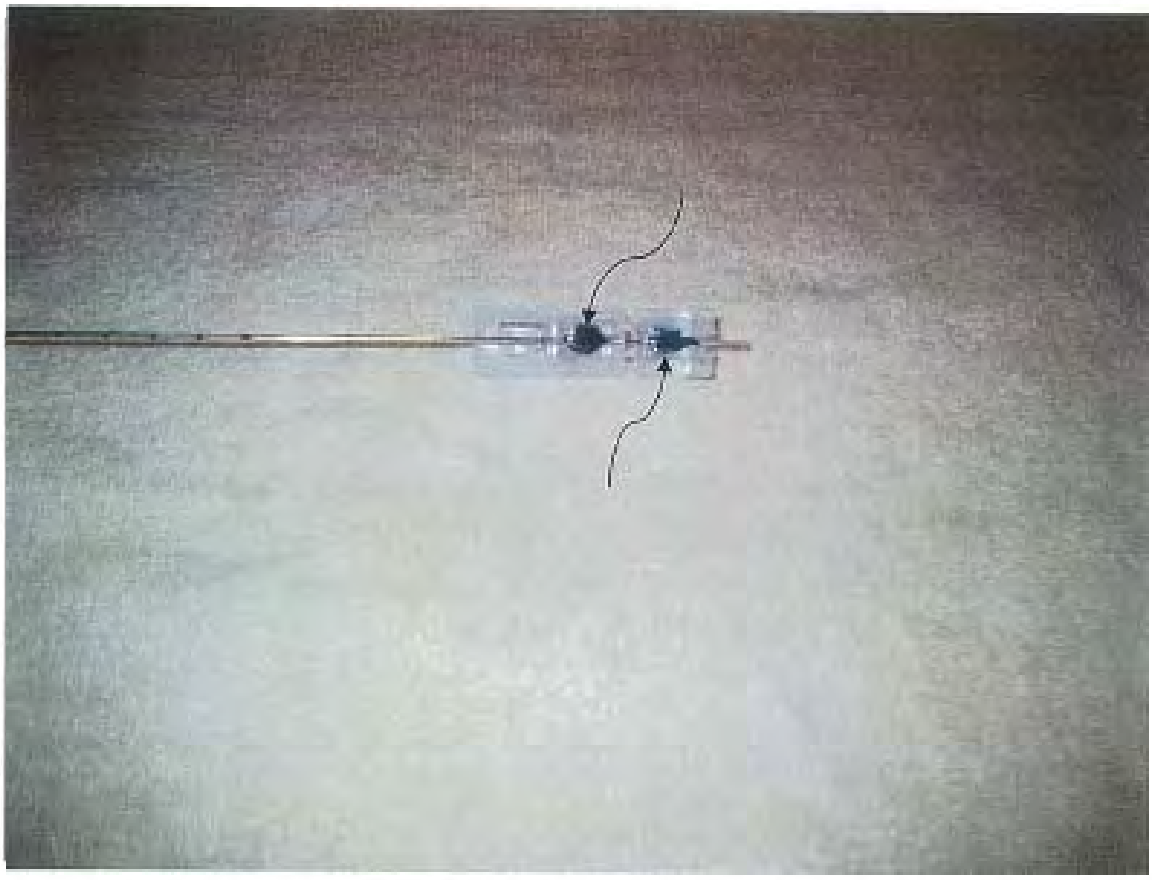

Figure 2 – Use of adhesive for bonding the cannula of a sample of the accused product to its guide. The adhesive drops (artificially darkened for this picture) are shown by the two arrows.

My understanding of the distinction between the definition and attributes of a **structure** versus an adhesive bond is supported by the following sources including the Internet, dictionary and several engineering textbooks that are directly related to the subject matter in dispute in this case. While these are contemporary sources, they are consistent with the understanding I've had with regard to these terms since 1989.

1 - Definition of "STRUCTURE "according to Merriam-Webster dictionary posted on the Internet":

Something put together by arranging or connecting an array of parts <the Egyptian pyramids are among the most remarkable *structures* ever built>

The arrangement of parts that gives something its basic form <the basic *structure* of all those tract houses is the same: basically, a box> — see FRAME

2 - Definition of "STRUCTURE" according to "Design of Machinery", 2nd Edition, by Robert L. Norton, McGraw-Hill, ISBN 0-07-048395-7, page 32:

"The degree of freedom (DOF) of an assembly of links completely predicts its character. There are only three possibilities. *If the DOF is positive, it will be a mechanism*, and the links will have relative motion. *If DOF is exactly zero, then it will be a* ***structure***, and no motion is possible. If the DOF is negative, then it is a preloaded structure."

3 - Definition of "STRUCTURE" according to "Theory of Machines and Mechanisms" Joseph Edward Shigley & John Joseph Uicker, Jr., McGraw-Hill, ISBN 0-07-056884-7, page 5:

"Some light can be shed on these definitions by contrasting them with the term ***structure***. A ***structure*** is also a combination of resistant (rigid) bodies connected by joints, but its purpose is not to do work or transform motion. A ***structure*** (such as a truss) is intended to be rigid. It can perhaps be moved from place to place and is movable in this sense of the word; however, it has no internal mobility, no relative motions between its various members."

4 - Definition of "STRUCTURE" according to "Engineering Mechanics, Statics", by Robert W. Soutas-Little & Daniel J. Inman, Prentice Hall, ISBN 0-13-769001-0, page 285:

"S***tructures*** are modeled as a number of rigid members or parts…" ***Structures*** may range in complexity and number of parts from the bridge to the pair of pliers shown in Figure 6.1. The bridge is made up of many parts, while the pair of pliers has only three parts."

5 - Definition of "STRUCTURE" according to "Theory and problems of Space Structural Analysis", Schaum's Outline Series, by Jan J. Tuma & M. N. Reddy McGraw-Hill, ISBN 0-07-065432-8, page 1:

"A space ***structures*** is a three-dimensional system (collection, set) of bars, plates and/or shells designed and built to carry loads and resist stresses."

In the case of the accused product, there is no standalone structure, nor is there any third member support that firstly is fabricated separately, and secondly attaches to the cannula in order to make it "connection-ready" for its guide. In the accused product, the connections between the cannula and the outer tube and their respective guides are achieved without intervention of a

separate structure. They are bonded by a droplet of an appropriate adhesive on the V-shaped trough of the guides.

In the accused product, the cannula and outer tube are directly bonded to their respective guides by adhesive. The droplet of adhesive that is used in the accused product does not fit any of the above definitions and attributes associated with a **structure** or **support.** As a result, a cannula mount is not literally present in the accused product.

Under the function-way-result test for determining whether an element is present under the doctrine of equivalents, the function in this case would be securing a cannula to a guide. The cannula mount of claim 7 of the '797 patent secures the cannula to the guide indirectly via a separate support or structure. As noted in column 9, lines 28-33, of the '797 patent, however, the cannula may be secured to the cannula mount either with our without adhesive. Further, the patent states that the cannula mount may be secured to the guide by adhesive ('797 patent, column 9, lines 40-43). It therefore stands to reason that the cannula mount must be some piece which indirectly attaches the cannula to the guide, and which is different from an adhesive. By contrast, as described above, the adhesive of the accused product secures the cannula and outer tube directly to their respective guides, without any intervening structure. As a result, the adhesive of the accused product and the cannula mount of claim 7 of the '797 patent do not achieve substantially the same result in substantially the same way.

Therefore, it is my opinion that the accused product does not include, literally or under the doctrine of equivalents, the foregoing element of Claim 7 of '797 patent.

XIII. THERE IS NO MANUALLY OPERABLE CHARGING MEMBER:

As noted above, claim 7 of the '797 patent recites the following:

> **"a manually operable charging member for moving the guide to the charged position against the urging of the coil spring"**

According to the Court's Order, the above term of claim 7 of the '797 patent is interpreted as:

> **"a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring."**

It is my opinion that the accused product does not feature this element or limitation literally or under the doctrine of equivalents.

As discussed above, the accused product uses a slider-crank mechanism for moving guides to a changed position against the urging of a coil spring. The Court found that the term "mechanism" is inconsistent with the common and ordinary meaning of "member" to someone skilled in the art. The Court further noted that "member" and "mechanism" cannot be treated as synonymous and that it cannot define "member" as including the alternative term "mechanism." My understanding of the terms mechanism and member agree with those expressed by the Court. As the accused product uses a mechanism to charge the instrument, the accused product does not literally include "a manually operable charging member" as recited by claim 7 of the '797 patent.

Further, the mechanism of the accused product cannot be considered to be the equivalent of "a manually operable charging member", as explained in detail below.

The **slider-crank mechanism** of the accused product works against the mechanical resistance of the coil spring during storage of elastic potential energy in the spring (charging phase.). Claim 7 of the '797 patent, however, recites a **member** for this purpose[2]. The

[2] Member 20 of Figure 1 or member 220 of '797 patent

distinction between the definitions and attributes of a **mechanism** versus a **member** is best revealed by referring to the following quotations from textbooks that are directly related to the matter of dispute in this case. Again, to the extent the following texts were authored after 1989, they reflect the same understanding that I had of the terms "member" and "mechanism" in 1989.

> "...Such kinematic chain, with at least one link fixed, become (1) ***mechanism*** if at least two other links retain mobility, or (2) ***structure*** if no mobility remains..."[3]
>
> "...A ***mechanism*** is the mechanical portion of a machine that has the function of transferring motion and force from a power source to an output. It is the heart of a machine... A ***mechanism*** can be considered rigid parts that are arranged and connected so that they produce the desired motion of the machine. .. ***mechanisms*** consist of connected parts with the objective of producing desired motion. A ***linkage*** is a ***mechanism*** where all parts are connected together to form a closed chain."[4]
>
> "... A ***kinematic chain*** is defined as: an assemblage of links and joints, interconnected in a way to provide a controlled output motion in response to a supplied input motion. A ***mechanism*** is defined as: a ***kinematic chain*** in which at least one link has been grounded or attached, to the frame of reference (which itself may be in motion)."[5]
>
> "...A ***mechanism*** is a combination of rigid or resistant bodies so formed and connected that they move upon each other with definite relative motion. An example is the crank, connecting rod, and piston of an internal-combustion engine..."[6]
>
> "... A combination of interrelated parts having definite motion and capable of performing useful work may be called a ***machine***. A ***mechanism*** is a component of a ***machine*** consisting of two or more bodies arranged so that the motion of one compels the motion of the others."[7]

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[3] **"Mechanism Design, Analysis and Synthesis"**, Volume I, 4rth Edition, Authors: Arthur G. Erdman, George N. Sandor, Sridhar Kota, Prentice Hall, **ISBN: 0-13-040872-7**, page 1.

[4] **"Machines & Mechanisms, Applied Kinematic Analysis"**, 2nd Edition, Author: David H. Myszka, Prentice Hall, **ISBN: 0-13-030680-0**, page 3.

[5] **"Design of Machinery, An Introduction to the Synthesis and Analysis of Mechanisms and Machines"**, 2nd Edition, Author: Robert L. Norton, McGraw-Hill, **ISBN: 0-07-048395-7**, page 27.

[6] **"Mechanisms and Dynamics of Machinery"**, 4rth Edition, Authors: Hamilton H. Mabie, Charles F. Reinholtz, John Wiley & Sons, **ISBN: 0-471-80237-9**, page 5

[7] **"Kinematics and Dynamics of Machinery"**, 3rd Edition, Authors: Charles E. Wilson, J. Peter Sandler, Prentice Hall, **ISBN: 0-201-35099-8**, page 1.

> "...Reuleaux defines a ***mechanism*** as an assemblage of resistant bodies, connected by movable joints, to form a closed kinematic chain with one link fixed and having the purpose of transforming motion..."[8]

The direct quotations presented above regarding the definition of a **mechanism** reveal that

1. A mechanism must have at least 3 members, one of which is fixed and defines the "ground". The Court accurately distinguished between the definitions of a ***mechanism*** versus a ***member*** in its Order.

2. The interconnected members of a mechanism enable the designer (inventor) to seek a specific kinematic arrangement for the ***mechanism*** so that she/he can provide a desired motion with targeted interacting force characteristics. Such a desired motion with targeted interacting force characteristics cannot be achieved by employing a single ***member*** of any kind or any shape. In other words, a ***member*** can never substitute the output features of a ***mechanism***.

Figure 3 shows a schematic of the slider-crank mechanism of the accused product at the beginning of the "charging phase" of the device. Here it can be noted that the particular **slider-crank mechanism** designed for the accused product has a very unique and innovative design concept for the living hinge that connects the connecting rod of the **mechanism** to its slider member. As noted previously, this living hinge is illustrated at **32** in Figures 1-C and 1-D of this report. In order to comply with DFM (Design-For-Manufacturing) aspects of the mass production of the accused product, the inventors have created the exact function a typical hinge by reducing the thickness the connecting rod at its point of contact to the slider link of the **mechanism**.

The **slider-crank mechanism** of the accused product has a useful functional attribute that is unique to **slider-crank mechanisms**. This feature specifically relates to the actuating force

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[8] **"Theory of Machines and Mechanisms"**, 2nd Edition, Authors: Joseph Edward Shigley, John Joseph Uicker, Jr., Mc-Graw Hill, Inc., **ISBN: 0-07-056930-4**, page 6.

that is needed to fully compress the coil spring in the accused product. A typical **slider-crank mechanism** has a force amplification feature that becomes more and more pronounced near the Top-Dead-Center[9] configuration of the **mechanism.** Figure 4 shows a schematic view of the **slider-crank mechanism** of the accused product at or near its Top-Dead-Center configuration. On one hand, this mechanism has its highest force amplification attribute at and near its Top-Dead-Center. On the other hand, the resisting force of a typical coil spring is a maximum when it is fully compressed. To take advantage of this force amplification characteristic of the **slider-crank-mechanism**, the accused product has been designed such that the spring is fully compressed when the mechanism is at its Top-Dead-Center. By contrast, the device disclosed by the '797 patent, having a single member **20** of its Figure 1 or member **220** of its Figure 5 totally lacks this very important and desirable force amplification feature. Figure 5 is a schematic view depicting the kinematic aspects and the **charging member** of claim 7 of the '797 patent.

I conducted a preliminary experiment (see Exhibit 3) on the coil spring of the accused product in order to determine its stiffness. This stiffness turned out to be about 12 pound-per-inch. In other words, if the spring is compressed one inch from its free length, the required force is about 12 pounds force. With no force amplification features, a compression of 1.5 inch of the spring requires 12 x 1.5 = 18 pounds force. As a result, the physician using a device fabricated according to the teaching of claim 7 of the '797 patent, with a spring of similar resistance, must apply 18 pounds force by hand to fully charge the device. By comparison, the force required to charge the accused product is a maximum of 4.35 pounds force. This is a factual distinction and an advantageous feature of the accused product over the device described by claim 7 of the '797

[9] At one instance of the cyclic motion of a **slider-crank mechanism** the crank and connecting members become co-linear relative to each other. In this position the slider member reaches its furthest point away from the crank member. Under this configuration the **mechanism** is said to be at its Top-Dead-Center.

patent. A force analysis and virtual work and kinematic analysis of the accused product and the device according to claim 7 of the '797 patent are attached as Exhibits 3 and 4, respectively.

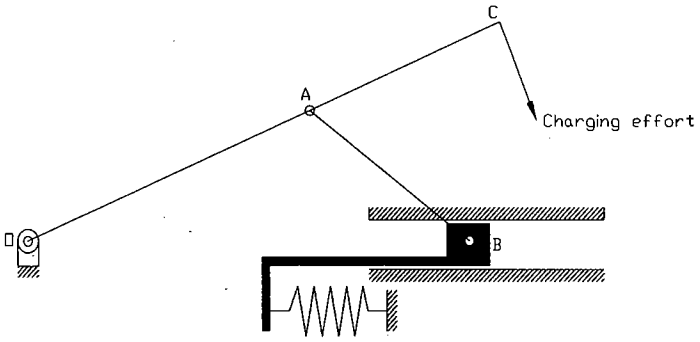


Figure 3 – A schematic view of the kinematical aspects of the accused product in a ready to be charged configuration

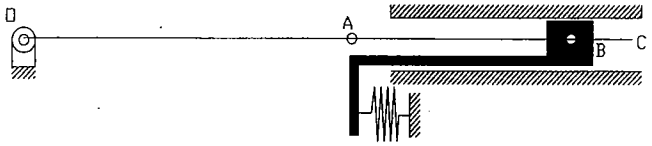


Figure 4 – Slider-crank mechanism of the accused product at its Top-Dead-Center configuration

Figure 5 – Kinematical configuration of the charging member of the '797 patent

The distinction between the **charging member** of claim 7 of the '797 patent and the **charging mechanism** of the accused product makes clear that they are not equivalents. More specifically, they do not perform substantially the same function in that the **mechanism** of the accused product provides force amplification, while the **member** of claim 7 of the '797 patent does not Furthermore, the above analysis clearly shows that the **mechanism** of the accused product and the **member** of claim 7 of the '797 patent operate in substantially different ways. The **charging member** has no ability to reduce the effort of the operator. The **slider-crank mechanism** of the accused product is designed to reduce the operator's effort. The **mechanism** also allows for a change in the direction of the force applied by the operator. The **charging member** has no such change in the direction of the force. Therefore, the charging member and the accused product's charging mechanism provide similar results in that they cause the spring to be compressed into a charged position. However, they perform this task using substantially different functions and do so in substantially different ways.

XIV. THERE IS NO RELEASE MEANS FOR RETAINING THE GUIDE IN THE CHARGED POSITION

As noted previously, claim 7 of the '797 patent recites the following:

> **"a release means for retaining the guide in the charged position"**

According to the Court's construction, the above term of claim 7 of the '797 patent is interpreted as a means plus function element in which the function is:

> **"retaining the guide in the charged position and releasing, or setting free, the guide from the charged position."**

The Court found that the function recited was "retaining the guide in a charged position and releasing, or setting free, the guide from the charged position." Order p. 30-31. The Court found that the corresponding structure was, with reference to Figures 1-4A of the '797 patent, the release lever **22, including the latching projection 102, the finger rest 96 and the mounting section 98, and, with respect to Figures 5-8A of the '797 patent, the release lever 222, including the latching protrusion 302, the finger rest (not marked by a reference number), and the mounting section 298.** Order p. 33.

Here, before any discussion on the matter of infringement, it is worthwhile to note that the arrangements proposed by '797 patent is not operational. According to the teaching of '797 patent a spot-weld (referred to by **104** in Figure 2 of the '797 patent) "flexibly" connects member **22** to exterior shell **26** of the proposed design. Just from the description of this spot-weld connection one could visualize that by pressing on the thumb-rest section **96** of member **22** the desired see-saw rocking motion of member **22** will not take place. The only action that may take place here is the downward bending of the thumb-rest **96** with section **98** and latch **102** of member **22** unaffected. This is an enablement issue of the device disclosed by patent '797.

It is my opinion that the retainer/releaser arrangements of the accused product is completely distinguishable from the **structure** that corresponds to the **means-plus-function** of claim 7 of '797 patent.

As shown in Section XIII of this report there are radical differences between the **charging member** of the claim 7 of the '797 patent and the **slider-crank charging mechanism** of the accused product. These radical differences can be found on the distinction between a **member** and a **mechanism**, the principle of operation of the two chargers of these devices and the performance characteristics of the two chargers (see Figure 5)

It is my opinion that as the two chargers are drastically different, their corresponding release/retaining means is likewise drastically different. Below is an elaboration of my analysis on this matter.

The means-plus-function of claim 7 of the '797 patent discloses a single piece **structure** shown by reference numeral **22** or **222** that corresponds to the release/retain function of the proposed device. See Figures 1, 4A, 5, and 8A of the '797 patent. The release/retain function of the accused product is accomplished by a multi-component arrangement shown in Figures 6, 7, 8. In the case of the accused product, it is my opinion that a multi-component release/retain arrangement, for which every single and separate component has a necessary function for achieving the final goal does not infringe directly or under the doctrine of equivalence on the release/retain arrangement of the device disclosed by claim 7 of '797 patent.

To further elaborate on this matter, I refer to Figure 1-F of this report, which shows one of the components of the accused product. The latching protrusion shown at **48** in this figure is the element that latches onto the slider link for retaining the guides in the charged configuration. This protrusion is then set free at the time of discharge. Figure 1-G of this report shows another component of the accused product. The step (shown at **46**) is the element to which the protrusion **48** of Figure 1-F latches on from which it is freed. This step is the second component the retainer and release arrangement of the accused product. Figures 1-D and 1-E of the accused product show an elongated release bar **38**. In an assembled product, this third component is sandwiched between the two guides and the slider link of the **slider-crank mechanism**. Figure 1-E shows the relative positions of these three components in a disassembled configuration.

From the above presentation, it is clear that the three-component retainer and release of the accused product is drastically different from the retainer and release lever disclosed by the

means-plus-function portion of claim 7 of the '797 patent. I rely on the Court's interpretation of this portion of claim 7 of '797 that clearly identifies a structure corresponding to the function of retain/release of the claim 7 of the '797 patent. Hence, it is my opinion that the accused product does not infringe directly or under the doctrine of equivalents on the means-plus-function portion of claim 7 of the '797 patent. I reserve the right to demonstrate this matter by using the actual components of the accused product in the court during the trial.

From the above discussion, it is clear that the three-component retainer and release of the accused product is drastically different, and therefore operates in a way that is substantially different, from the single piece retainer and release recited by the means plus function portion of claim 7 of the '797 patent and disclosed in the '797 patent.

It is therefore my opinion that the accused product does not include this means-plus-function element of claim 7 of the '797 patent literally or under the doctrine of equivalents.

Furthermore, the Plaintiff's Expert, John R. Haaga, M.D. rendered opinion on the matter of infringement of the accused product on claim 7 of '797 patent. On page 22, paragraph 50 of his report, dated January 11th, 2008, Dr. Haaga states:

> As illustrated below in Figure 12 and 13, the BioPince products include a strut or lever stage 60 provided with a release lever 65 that includes a latching projection 70 and a mounting section 75. Applying the claim construction provided by the Court, the latching projection 70 of the release lever 65 is releasably engaged to a shoulder 80 in an opening 85 in the charging member 55, such that : i) when the latching projection 70 engages the shoulder 80 of the charging member 55, the guide 40 is retained in its charge position and ii) when the latching projection 70 is disengaged from the shoulder 80 in the opening 85 of the charging member 55 (e.g., by lifting up on the charging member 55 at the site where the strut 60 pivotally connects to the charging member 55), the guide 40 is released or set free from its charged position. Based at least on the foregoing, it is my opinion that this structure (i.e., the release lever 65 that includes a latching projection 70 and a mounting section 75) represents an equivalent structure of the corresponding structure set forth

> in the Court's claim construction. Accordingly, it is my opinion that the BioPince products satisfy this limitation.

This opinion is factually flawed and it incorrectly states the design and the principle of operation of the accused product. It is beyond factual dispute that the release/retaining arrangement of the accused product does not include any of the components that the Plaintiff's Expert has referred to in his above quoted statements.

1. The combination of elements 60, 65, 70, 75, 80, and 85 that this expert is referring to as the components that are read on by claim 7 of the '797 patent have been designed to keep the crank arm of the slider crank mechanism fixed to the exterior shell (handle of the device during its intended use. These components are not designed to function or to be used as release/retainer arrangement of the accused product.

2. The release/retain arrangement of the accused product is housed well inside of the exterior shell (handle) of the device. Referring to Figure 6, 7, 8, and 9 of this report, the release/retain components, and their relative arrangement, are clearly shown in these figures. On pages 37 and 38 of this report I have explained the principle of operation of the release/retain arrangement of the accused product, including the specific function of each component. The design and principle of operation of the release/retain arrangement of the accused product is drastically different with those of the claim 7 of '797 patent, both literally and under any doctrine of equivalents.

The designers of the accused product neither meant nor propose to use the elements that are numbered by the Plaintiff's Expert as: 60, 65, 70, 75, 80, and 85 for the purpose of releasing/retaining the elastic potential energy of the coil spring of the accused product. Plaintiff's Expert is either not familiar with mechanical principles, or he is suggesting a **misuse** of the accused product in a way that is not only unsafe for the patient, but also is against the intended design and performance of the accused product. Following the use described by Plaintiff's Expert, upon a discharging of the accused product a violent and uncontrolled discharged of the spring's energy will ensue while the stylet is inserted in the patient. Such a

violent and chaotic discharge of energy will likely cause erratic movement of the stylet, the discharging cannula and the outer tube and is extremely deleterious for the patient, for the device, and for the operator of the device

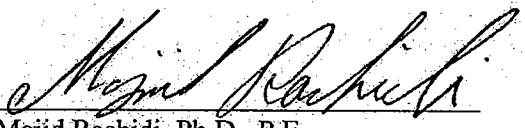
XV. CONCLUSION

Based on the material I have presented in this report, it is my opinion that the accused product of the Defendant does not infringe claim 7 of U.S. Patent 5,025,797.

I do not know either parties of this dispute. I have no vested interests in the outcome of this dispute.

I reserve the right to clarify, amend, and supplement my opinions, and to express further opinions, based upon the disclosure of Dr. Baran's experts' opinions and upon the development of additional information as this case proceeds to trial.

Dated: February 22, 2008

By: 
Majid Rashidi, Ph.D., P.E.